MEDDAC Regulation 40-26

Medical Services
Anthrax Vaccine Immunization Program (AVIP) Implementation Plan

1 October 2001

Department of the Army
Headquarters
United States Army Medical Department Activity
2480 Llewellyn Avenue
Fort George G. Meade, Maryland 20755-5800

For the Commander:

JEROME PENNER III
LTC, MS
Deputy Commander for Administration

Official:

JOHN SCHNEIDER
Adjutant

History. This is the initial printing of this publication.

Summary. This regulation outlines the roles, responsibilities, and procedures for implementing phases I and II of the Army AVIP for the U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC).

Applicability. This regulation applies to the MEDDAC headquarters; e.g., Kimbrough Ambulatory Care Center (KACC), and all outlying U.S. Army health clinics (USAHCs).

Proponent. The proponent of this regulation is the Chief, Preventive Medicine Service (PM).

Suggested improvements. Users of this publication are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to the Commander, U.S. Army Medical Department Activity, ATTN: MCXR-PM, Fort George G. Meade, MD 20755-5800.

Distribution. Distribution of this publication is by electronic medium only.

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* This update supersedes MEDDAC Regulation 40-26, dated 6 April 1999.

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Chapter 1
Introduction

1-1. Purpose
This regulation prescribes responsibilities, policies and procedures for implementing Phase I and Phase II of the AVIP within the MEDDAC.

1-2. References
Required and related publications are listed in appendix A. Prescribed and referenced forms are also listed in appendix A.

1-3. Explanation of abbreviations and terms
Abbreviations and special terms used in this regulation are explained in the glossary.

1-4. Pronouns
Use of the pronouns he and his include she and hers.

Chapter 2
Responsibilities

2-1. The MEDDAC Commander
The MEDDAC Commander will—

a. Ensure that the AVIP is implemented within the MEDDAC in accordance with (IAW) Department of the Army (DA) and North Atlantic Regional Medical Command (NARMC) guidelines.

b. Provide enforcement for the program, as outlined in this regulation.

c. Provide immunization support to units of the Reserve Component (RC) as described in this regulation and the NARMC AVIP Plan. (The term "Reserve Component" is explained in the glossary.)

d. Provide immunization support to personnel from other services IAW Department of Defense (DoD) guidance.

e. Ensure that MEDDAC personnel are briefed using the DA briefing prior to receiving the anthrax vaccine.

f. Ensure that health care providers have received the Anthrax Healthcare Providers Briefing IAW this regulation.

2-2. Medical treatment facility (MTF) commanders and directors
MTF commanders and directors includes the MEDDAC Commander and all commanders and directors of the MEDDAC's outlying USAHCs. They will—

a. Oversee the AVIP for their individual host installations and areas of concern.

b. Institute an AVIP Health Communication Team (HCT) as well as a Medical Protection System (MEDPROS) Configuration Control Team (MEDPROSCCT).

c. Upon request, report their AVIP status to the MEDDAC Commander or the commander's representative.

d. Implement procedures to monitor MEDPROS data for ensuring that personnel requiring the anthrax vaccine receive it in a timely manner.

e. Establish procedures to ensure the anthrax immunization schedule is followed and that medical records are properly documented prior to deployment to high risk areas IAW DA guidance.

f. Establish procedures to ensure all MTF active duty personnel inprocessing and outprocessing the MEDDAC process through the MTF’s immunization clinic to be screened for anthrax immunization status.

g. Facilitate a mechanism to ensure personnel reassigned to high risk areas are identified during the installation levy briefing and referred to the immunization clinic to begin their anthrax immunization series no later than one month prior to departure.

2-3. The Deputy Commander for Clinical Services (DCCS)

The DCCS will—

a. Oversee implementation of the AVIP within the MEDDAC.

b. Provide personnel resources from clinical services to support the program, as outlined in this regulation.

c. Establish a MEDDAC AVIP Oversight Board, consisting of a chairperson and panel of experts, and two subordinate teams; an HCT and a MEDPROSCCT.

2-4. The Chief, PM

The Chief, PM will—

a. Serve as the Anthrax Program Coordinator for the MEDDAC and as chairperson of the MEDDAC's MEDPROSCCT.

b. Submit reports of validated adverse reactions to the Army Medical Surveillance Activity (AMSA) using the automated reportable events system.

c. Ensure the medical and shot records of personnel inprocessing to the MEDDAC are screened for the anthrax immunization during the Birthmonth Annual Training and/or when inprocessing through the Occupational Health Clinic.

d. Review this regulation at least annually and update it as required.

2-5. The Chief, Logistics Division (LOG)

The Chief, LOG will—

a. Oversee all logistical operations concerning the MEDDAC AVIP at KACC, Kirk USAHC and Fort Detrick USAHC.

b. Receive and forward off-line vaccine requisitions from supported units to the U.S. Army Medical Materiel Agency (USAMMA) and notify USAMMA upon receipt of vaccine.

c. Obtain all ancillary supplies requested by the Allergy/Immunization Clinic and supported units to conduct anthrax immunizations.

d. Submit requests for reimbursement for ancillary supplies to the Assistant Chief of Staff, Logistics and Acquisition, NARMC.

2-6. The Chief, Pharmacy Service

The Chief, Pharmacy Service will—

a. Submit the Vaccine Adverse Event Reporting System-1 (VAERS-1) report to the Food and Drug Administration Vaccine Adverse Event Reporting System for each adverse event.

b. Provide a copy of the VAERS-1 report on validated adverse reactions to AMSA.

c. Coordinate the review and validation of all reports of adverse vaccine reactions submitted to the Pharmacy Service by MEDDAC health care providers.

2-7. The Chief, Operations & Staff Development Division (OSD)

The Chief, OSD will—

a. Track and report to the MEDDAC Commander and AVIP Oversight Committee the status of individuals delinquent on their anthrax immunizations throughout the MEDDAC's catchment area.

b. Disseminate AVIP information received through operational channels.

c. Implement procedures to monitor MEDPROS data at KACC for ensuring that personnel receiving the anthrax vaccine at Fort Meade receive it in a timely manner. Assist other MEDDAC MTFs in this function when required.

d. Accomplish all non-clinical reporting to NARMC, as required.

2-8. The Chief, Military Personnel Division (MPD)

The Chief, MPD will ensure all active duty personnel inprocessing and outprocessing KACC process through the Allergy/Immunization Clinic to be screened for anthrax immunization status.

2-9. The Chief, Information Management Division (IMD)
The Chief, IMD will ensure that MEDPROS access is available in the MEDDAC and provide technical assistance for any operational hardware problems relating to the Medical Occupational Data System (MODS).

2-10. The Adjutant
The Adjutant, as the MEDDAC's Public Affairs Officer, will—

a. Respond to media inquiries IAW with guidance received from the NARMC and U.S. Army Medical Command (MEDCOM) public affairs offices.

b. Coordinate media photo opportunities IAW MEDCOM Public Affairs guidance.

c. Provide media coverage updates to the NARMC and MEDCOM public affairs offices when required.

2-11. Chiefs and noncommissioned officers in charge (NCOICs) of immunization clinics
Chiefs and NCOICs of the MEDDAC's immunizations clinics will—

a. Provide pre-immunization anthrax vaccine briefings IAW the DA AVIP for individual soldiers as they arrive at the immunization clinic to receive their initial anthrax immunizations.

b. Administer the anthrax vaccine IAW this regulation and the DA AVIP.

c. Record the immunization data in the patients' medical records on Standard Form (SF) 601 (Health Record - Immunization Record); on the patient's Health and Human Services (HHS) Form Public Health Service (PHS) 731 (International Certificates of Vaccination); and, within 24 hours, in MEDPROS.

Chapter 3
General

3-1. The anthrax threat
Anthrax is a highly lethal biological weapon when used on the battlefield. Counter-measures against anthrax exposure include the use of personal protective measures, including the wearing of mission-oriented protection posture (MOPP) gear and the use of post-exposure antibiotics. However, the most effective countermeasure is pre-exposure immunization with the anthrax vaccine.

3-2. Institution of the AVIP
On 15 December 1997, in recognition of the anthrax threat (see para 3-1 above), the Secretary of Defense announced plans to vaccinate all US military personnel against anthrax. DA was designated as the DoD executive agent for implementation of the AVIP.

3-3. AVIP concept of operations
The Vice Chief of Staff of the Army approved the Army AVIP Plan on 28 April 1998, and the Secretary of Defense approved the Total Force AVIP Plan on 18 May 1998. NARMC distributed a draft AVIP Plan for the NARMC on 8 June 1998. The concept of operations for the Army AVIP calls for vaccination of the Total Army; i.e., the Active and Reserve Components, and critical DA civilians and DoD contractors to be executed in three phases over a 7- to 8-year period. The phases are described as follows:

a. Phase I. Forces deploying to the high threat areas of Southwest Asia (Bahrain, Israel, Jordan, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen), and Northeast Asia (Korea). This phase will include personnel rotating into these high threat areas and personnel on temporary duty in these areas. Phase I began August 1998 and is projected to continue through the 30 September 1999. The MEDDAC's priorities during this period are—

(1) Personnel deploying into high threat areas.

(2) Continuation of immunizations for soldiers who began the series while deployed to high threat areas.

(3) Establishment of a viable MEDDAC AVIP that provides anthrax immunization capability across the MEDDAC's area of concern.

b. Phase II. Early deploying forces (C to C+35) into the high threat areas of Southwest Asia and Northeast

Asia. Projected time period is the 4th quarter FY99 to FY03. It is anticipated that only a few units in the MEDDAC's catchment area will fall into the Phase II category. All eligible units were identified by February 1999.

c. Phase III. The remainder of the Total Army, accessions, and program sustainment. Projected to begin in FY03.

3-4. Command responsibility for AVIP

The DoD AVIP is a command responsibility as part of force protection. Commanders are responsible for its implementation, education of their personnel, and accurate and timely tracking of the anthrax immunization series.

Chapter 4
The Anthrax Immunization Series, Vaccination Requirements, Immunization Tracking, and Funding and Ordering Vaccine

4-1. The anthrax immunization series

The Anthrax Vaccine is a 6-shot series administered over a period of 18 months. Primary, immunization consists of three subcutaneous injections of 0.5ml each, given 2 weeks apart (weeks 0, 2 and 4) followed by three additional subcutaneous injections of 0.5ml each, given at 6, 12, and 18 months. Subsequent booster injections of 0.5ml given at 1-year intervals are required to maintain immunity. DoD policy states that, for force protection purposes, a service member will be considered deployable if he is enrolled in the 6-shot series, regardless of whether or not he has completed the series. However, it is desirable that all personnel assigned to high threat areas receive their first three shots prior to deployment. In those rare instances when an individual is not able to take or continue the anthrax series due to medical or administrative reasons, he will still be deployable.

4-2. Vaccination requirements for military personnel

Unless specifically exempted by this regulation or by competent medical authority detailed in this regulation, military personnel are required to initiate and complete the immunization schedule. As with all immunizations, military personnel do not have the option to be immunized. IAW AR 600-20, commanders can order their soldiers to be immunized. Although each case will have to be determined on its own merits, soldiers refusing an order may face disciplinary action under the Uniform Code of Military Justice.

4-3. Vaccination requirements for DA civilians and DoD contractors

Immunization against anthrax will also be provided for those DA civilians and DoD contractors whose duties place them at risk for exposure to anthrax used as a biological weapon in a combat or operational setting. The unit commander determines which employees are at sufficient risk to warrant immunization. Immunization of DA civilians and DoD contractors is voluntary and will be administered without charge to the employee/contractor. In most instances, employee/contractor immunization is by consent, however, in certain circumstances, anthrax immunization might be determined by the appropriate authority to be a condition of employment.

4-4. Vaccination of Professional Filler System fillers (PROFIS)

Army Medical Department (AMEDD) personnel designated as PROFIS will be vaccinated in the same priority as the unit to which they are designated as fillers.

4-5. Immunization tracking

Tracking the status of anthrax immunization series is a command responsibility. The Army's immunization tracking system is MEDPROS; a subset of MODS. MODS resides on the mainframe computer system at the

Pentagon. MEDPROS will become the legacy system to the quad-service immunization tracking system within the Preventive Health Care System in the Composite Health Care System (CHCS) II. Other services' military members, DoD civilian employees and DoD contractors may receive their vaccinations at Army MTFs IAW this regulation and will be tracked using MEDPROS. MEDPROS will report anthrax immunization data to the Defense Enrollment Eligibility Reporting System (DEERS). Other services will gain visibility of their members vaccinated in Army facilities from DEERS reports. MEDPROS will also read data from DEERS and record the evidence of soldiers receiving anthrax immunizations from another service. DEERS is the central repository for anthrax immunization data for DoD.

4-6. Funding and ordering vaccine

Anthrax vaccine is centrally funded by the Joint Program Office - Biological Defense, and is stored at the manufacturer, Michigan Biological Products Institute. Ancillary supplies will be funded from Defense Health Program funds. Units will requisition the vaccine based on the DA prioritized unit list. Due to the 1-year shelf life of the vaccine (once it leaves the manufacturer), units will submit their initial requisition for the first three shots only.

Chapter 5
Pre-vaccination Information Requirements, Procedural Guidance, and Adverse Event Reporting

Section I
Required Briefings

5-1. Briefing of health care providers and staffs

a. Health care providers and staffs play key roles in this program, both in its execution as well as providing expert advice to soldiers and commanders. They must become familiar with all aspects of anthrax and the Anthrax Vaccine Adsorbed. The DA AVIP Providers Brief will be provided to all health care providers who administrate the immunization and to all primary care providers to include physicians, nurse practitioners and physician assistants. A copy of the DA AVIP Commanders Brief is available to all MEDDAC health care providers via the NARMC home page at http://www.narmc.amedd.army.mil.

b. The Walter Reed Health Care System has established an electronic consultation group within CHCS called "Ask Anthrax/Vaccine Questions." This group, headed by the Walter Reed Army Medical Center (WRAMC) Chief, Department of Allergy and Immunology, consists of staff from that department plus WRAMC's Chief, Preventive Medicine Service and Chief, Infectious Disease Service and his/her staff. This is a confidential group that can address patient-specific problems and coordinate expedited consultations for waivers should this be needed. This group will also be used for clinical problem solving and continuing education.

5-2. Briefing of vaccine recipients

Prior to individuals receiving their first anthrax vaccinations, the MTF commander/director and the medical staff will ensure that vaccine recipients are provided adequate information on the vaccine, to include its safety, its benefits, and the need for adherence to the immunization schedule. For MEDDAC personnel and other personnel receiving anthrax immunizations within MEDDAC MTFs, the required briefing will be provided by the clinic administering the vaccine. Prior to the first anthrax immunization, a written copy of the Anthrax Vaccine Commander's Briefing will be given to patients to read. After reading it, patients will be given the opportunity to address questions to the clinic physician. Patients will then sign a briefing compliance roster indicating that they have understood the briefing and had all questions answered prior to receiving the anthrax immunization. Active duty personnel, DA civilians and DoD contractors will also be given a copy of the relevant informational tri-fold, "What Every Service Member/Person Needs to Know About the Anthrax Vaccine," prior to receiving the vaccine.

Section II
Procedural Guidance for Administration of Anthrax Vaccine

5-3. Immunization procedures
The anthrax vaccine will be administered during normal duty hours in the immunization clinics of KACC, Kirk USAHC, Dunham USAHC, and Fort Detrick USAHC. All patients must bring their outpatient medical records (OMR), HHS PHS Form 731, and medical out-patient card.

5-4. Administering the vaccine
A description of the Anthrax Vaccine Adsorbed is at appendix B. Anthrax vaccine will be administered to the patient using a 27 gauge needle, 1/2 inch length with the tuberculin syringe. The immunization will be given subcutaneously rotating anatomic sites for each injection in the series. Anthrax vaccine may be administered concurrently with other common immunizations but separate syringes and different anatomic sites must be used. Anthrax vaccine will not be syringe mixed with any other product. Specific technical information for proper immunization delivery procedures can be found in the NARMC AVIP Plan, annex C, and will be explicitly followed.

5-5. Policy regarding unintended deviation from the anthrax immunization schedule
Guidelines for administering the anthrax vaccine to patients who have deviated from the approved anthrax immunization schedule are contained in appendix C.

5-6. Contraindications, warnings and precautions for anthrax vaccine administration
A description of the contraindications, warnings and precautions for administering the anthrax vaccine is at appendix D.

Section III
Records Maintenance

5-7. Medical records
a. A permanent entry will be made on SF 601 in the patient's OMR after each dose of anthrax vaccine is administered. The entry will include the date of immunization, name of the vaccine, manufacturer, lot number, series number, dose and route of administration, site of administration; for example, right anterior upper arm, and name of physician provider and nursing provider involved in delivery. The immunization will also be noted on the patient's HHS PHS Form 731.

b. Upon deployment, anthrax immunizations will be transcribed onto DA Form 8007 (Individual Medical History).

c. Local quality control and quality assurance measures IAW AR 40-68 shall be implemented to ensure the accuracy of medical records entries discussed in paras a and b.

d. A copy of this information will be maintained for at least two years in the files of the immunization clinic that administered the anthrax vaccine so that if electronic information is questioned, validation can be obtained from the written copy.

5-8. The automated immunization tracking system
All anthrax immunizations will be recorded in MEDPROS, the Army's automated immunization tracking system, within 24 hours after the immunization has been administered. This is IAW the NARMC AVIP Plan.

Section IV
Adverse Reactions to Anthrax Vaccine

5-9. What are the known adverse reactions to anthrax vaccine?
A description of reported adverse reactions to Anthrax Vaccine Adsorbed is at appendix E.

5-10. Documenting adverse reactions (events) to anthrax vaccine

a. All severe adverse reactions to anthrax vaccine will be documented in the individual's OMR on SF 600, Health Record - Chronological Record of Medical Care. Mandatory information consists of identification of the vaccine, the lot number and manufacturer, the date of administration, the name and location of the medical facility, and the type and severity of the reaction.

b. All adverse reactions resulting in hospitalization or time lost from duty for more than 24 hours must be reported as soon as possible.

c. Less severe reactions that are suspected to have resulted from contamination of vaccine lots must also be reported IAW AR 40-562.

d. All severe adverse reactions to the anthrax vaccine (see paras b and c) should be reported as soon as possible to the WRAMC Allergy-Immunology Clinic during duty hours. During non-duty hours, the WRAMC on-call Allergist-Immunologist will be notified.

5-11. VAERS

a. Adverse events must be reported to HHS VAERS using the VAERS-1 form. VAERS-1 forms and information can be obtained from the WRAMC Allergy-Immunology Clinic or KACC Pharmacy Service. Forms and information are also available online via the internet at http://www.fda.gov/cber/vaers.html. The attending physician or any other member of the medical staff who observes the adverse event will immediately complete a VAERS-1 report. If the person completing the report is not the attending physician, he will submit it to the attending physician expeditiously.

b. The attending physician will submit the completed the VAERS-1 report to the MTF's pharmacy, which will review and validate the report.

c. Chief of MTF pharmacies will mail valid VAERS-1 reports to the following address:

VACCINE ADVERSE EVENT REPORTING SYSTEM
PO BOX 1100
ROCKVILLE MD 20849-1100

5-12. Army reportable events system reporting

a. The Chief, Pharmacy Service at KACC will provide a copy of the VAERS-1 report to the Army Medical Surveillance Activity (AMSA) at the following address:

ARMY MEDICAL SURVEILLANCE ACTIVITY
US ARMY CENTER FOR HEALTH PROMOTION
AND PREVENTIVE MEDICINE
BUILDING T-20
WALTER REED ARMY MEDICAL CENTER
WASHINGTON, DC 20307-5100

b. Valid reportable adverse reactions will also be reported to the MEDDAC PM Communicable Disease Section, ATTN: Mrs. Virginia Taylor, for submission to the AMSA using the automated reportable events system.

c. AMSA will also receive adverse reaction reports from each military service through the Defense Medical Surveillance System and provide quarterly status reports to MEDCOM.

5-13. Adverse event reports from RC units

Adverse event reports from RC units will be filed through command channels to the appropriate AMEDD regional medical command. The Chief, Pharmacy Service at KACC will forward reports for units supported by the MEDDAC to WRAMC for review and appropriate submission.

Chapter 6
Tracking and Enforcement of AVIP Compliance, In and Outprocessing, and Logistics

6-1. AVIP tracking and enforcement of compliance

a. The DA AVIP is a command responsibility as part of force protection. The MEDDAC Commander is responsible for its implementation, education of applicable personnel, and tracking of the anthrax immunization series.

b. Each MTF that administers the anthrax vaccine will be responsible for tracking the progress of all active duty personnel who have been identified to receive the anthrax vaccine series by the MTF. This tracking responsibility extends to all military personnel assigned to the MTF's host installation and within the MTF's catchment area. The MTF will track each such service member's progress through the anthrax vaccine series to ensure the immunizations are administered IAW the immunization schedule contained in this regulation and the NARMC AVIP Plan.

c. Unless specifically exempted by this regulation or by the medical staff of the WRAMC Department of Allergy and Immunization, service members who are required to be immunized against anthrax will be required to initiate and complete the anthrax immunization series. Service members who refuse the immunization due to medical concerns will be seen initially by a uniformed medical officer in a non-confrontational patient-physician encounter. If the service member's concerns cannot be adequately addressed, the patient will be referred to an allergist in the WRAMC Allergy Immunology Clinic before any administrative actions are taken. The medical staff of the WRAMC Department of Allergy and Immunology will serve as the medical exemption authority for anthrax immunizations.

d. The effect on a DA employee who refuses immunization when indicated will be determined by the supervisor and commander in conjunction with representatives of the servicing Civilian Personnel Office. Refusal of anthrax immunization must be documented in the employee’s personnel record and the occupational health record.

6-2. In and outprocessing

MTF commanders will coordinate with their host installations to ensure that all active duty personnel who inprocess and outprocess the installation are required to process through the supporting MTF, where their anthrax immunization status will be screened. MEDDAC MTFs that are not authorized to give the anthrax vaccine will notify the closest supporting MEDDAC MTF authorized to give the vaccine concerning the status of any soldiers who are required to begin the series at their installations. MTF commanders will also coordinate with their installation's U.S. Army Garrison to ensure that active duty personnel being transferred or deployed to any area listed in para 3-2a above are informed at their levy briefings that they need to start the anthrax immunization series.

6-3. Logistics

MTF logistical activities will requisition anthrax vaccine from the US Army Medical Materiel Agency and procure ancillary immunization supplies. All anthrax vaccine will be properly stored by logistics and delivered directly to the MTF immunization clinic upon request.

Chapter 7
The MEDDAC Anthrax Vaccine Immunization Program (AVIP) Oversight Board and Subordinate Teams

7-1. The MEDDAC Anthrax Vaccine Immunization Program (AVIP) Oversight Board

The MEDDAC AVIP Oversight Board will consist of the following members and will provide oversight for the development and implementation of the AVIP for the MEDDAC:

a. DCCS - Chairperson.

b. Chief, PM.
c. Chief Nurse.
d. Chief, Primary Care (or designee).
e. DCCS, Kirk USAHC.
f. Chief Nurse, Dunham USAHC.
g. Chief Nurse, Fort Detrick USAHC.
h. Chief, OSD.
i. Adjutant.
j. Representative, Information Management Division (KACC).

7-2. Health communication teams (HCTs)

Each MTF authorized to administer anthrax immunizations (see para 5-3 above) will create an HCT. The HCT will, upon request, assist the MTF commander to educate his personnel about the AVIP, brief health care providers IAW this regulation, and coordinate and direct all publicity and patient education regarding the AVIP program. The following individuals will make-up the KACC HCT and will assist other HCT's at other MEDDAC MFTs upon request:

a. Chief, PM - Chairperson.
b. Chief, Primary Care (or designee).
c. Adjutant.

7-3. MEDPROS configuration control teams (MEDPROSCCTs)

a. Each MTF authorized to administer anthrax immunizations (see para 5-3 above) will create a MEDPROSCCT.

b. The MEDDAC MEDPROSCCT will oversee the implementation and quality assurance of the MEDPROS AVIP automated immunization tracking system. The MEDPROSCCT, at KACC, will consist of the following members:

(1) Chief, PM, Chairperson.
(2) Representative, OSD.
(3) Chief, Patient Administration Division.
(4) Chief, Military Personnel Division (will participate only as required).
(5) Representative, Information Management Division.

b. The MEDPROSCCTs at the other MTFs authorized to administer the anthrax immunization will be configured similarly to the MEDDAC MEDPROSCCT. (See para a.)

c. The MEDDAC MEDPROSCCTs will assist the MEDPROSCCTs at the subordinate MTFs as required.

Appendix A
References

Section I
Required Publications

AR 40-68
Quality Assurance Administration. (Cited in para 5-7.)

AR 40-562
Immunizations and Chemoprophylaxis. (Cited in para 5-10.)

NARMC Plan 98-01
Anthrax Vaccine Immunization Program Plan. (Cited in paras 3-2, 5-2, 5-4 and 5-8.)

Section II
Related Publications

AR 600-20
Army Command Policy

The Department of the Army Anthrax Vaccine Immunization Program Plan

Memorandum of Understanding between the U.S. Army Medical Command and U.S. Army Reserve Command, dated 11 May 1995.

The Total Force Anthrax Vaccine Immunization Program Plan

Section III
Referenced Forms

DA Form 8005-series
Outpatient Medical Record

DA Form 8007
Individual Medical History

HHS Form PHS 731
International Certificates of Vaccination

SF 600
Health Record - Chronological Record of Medical Care

SF 601
Health Record - Immunization Record

Appendix B
Description of Anthrax Vaccine Adsorbed

B-1. Anthrax Vaccine Adsorbed is a sterile product made from filtrates of microaerophilic cultures of an avirulent, nonencapsulated strain of *Bacillus anthracis* that elaborates the protective antigen during the growth period. The cultures are grown in a synthetic medium. The vaccine was approved by the Federal Drug Administration (FDA) in 1970 for use in humans to promote increased resistance to *B. anthracis* by active immunization. Anthrax vaccine is manufactured by the Michigan Biologic Products Institute under FDA Establishment License No. 99.

B-2. The vaccine final product is prepared from the sterile filtered culture fluid and contains no more than 2.4 milligrams (mg) of aluminum hydroxide (equivalent to 0.83mg aluminum) per 0.5ml dose. Formaldehyde, in a final concentration not to exceed 0.02%, and benzethonium chloride, 0.0025%, are added as preservatives. The potency of this product is confirmed according to the US Food and Drug Regulations (21 Code of Federal Regulations 620.23, now rescinded): Additional Standards for Anthrax Vaccine Adsorbed.

B-3. The vaccine is supplied in 5.2ml vials containing 10 doses each. Vaccine should be stored and shipped

under refrigeration (2 - 8 degrees Centigrade, 35.6 to 46.4 degrees Fahrenheit). Do not freeze. Once opened, properly stored vials may be used until the expiration date. Gently shake vial before use to assure homogeneous distribution of contents. Inspect contents for particulate matter or discoloration.

B-4. Indications and usage. Immunization with Anthrax Vaccine Adsorbed is recommended for individuals with a high risk of exposure to *B. anthracis*. It has been used in private sectors to immunize individuals who may come into contact with contaminated animal products (e.g., hides, hair or bones), individuals conducting diagnostic/ research activities at risk of coming into contact with the spores, and individuals (e.g., veterinarians) who may handle infected animals.

Appendix C
Policy Regarding Unintended Deviation from Anthrax Immunization Schedule

C-1. Full immunization with Anthrax Vaccine Adsorbed requires six doses to be administered over an 18-month period. Doses will be administered according to the following schedule (the first dose is given at "week 0"): weeks 0, 2, 4; and then at 6, 12, and 18 months. Yearly boosters will be administered thereafter to maintain immunity. This schedule is the only regiment shown to protect humans against anthrax.

C-2. The full immunization schedule, as described above, is a matter of DoD policy. Unit commanders are responsible for assuring that their personnel are available at the appropriate time for immunization. Although the effect of specific deviations from this schedule on vaccine efficacy is unknown, in general, the greater the deviation the less certain the protective effect. Although much of the guidance described below addresses late or missed doses, compressing or accelerating the vaccine series must also be avoided.

C-3. The following procedure will be followed for individual variation from the above schedule:

a. Once the schedule has begun, if a dose cannot be given at the appropriate time interval, administer it as soon as possible. Base the timing of all subsequent doses on the date the last dose was given, not when it was originally scheduled. For example, if the second dose, due 2 weeks after the first, is missed. The dose is given at the earliest opportunity. Two weeks after that, the third dose is given; the fourth dose five months after the third, and so on.

b. Annual boosters that are missed should be continued at the earliest possible date, adjusting the subsequent booster schedule accordingly.

c. It will not be necessary to re-start the entire primary series unless an extraordinary length of time (i.e.; 2 years or more) has elapsed since the most recent dose (see para e). The primary series of six doses must be completed only once, even if 2 or more years elapse between "booster" doses. Provide the next booster dose at the earliest possible date and continue to follow the prescribed schedule.

d. This guidance is intended for the rare exception where immunization is inadvertently missed. The immunization schedule as described in para C-1 is DoD policy.

e. Personnel who received anthrax vaccine during Operation Desert Shield/Desert Storm in 1991, but did not complete the 6-dose series, will restart the series. As stated above, all human efficacy data were derived from a study using the licensed immunization schedule. There is no data to determine the effects of a gap of seven or more years between doses.

Appendix D
Contraindications, Warnings, and Precautions for Anthrax Vaccine Administration

D-1. Contraindications

A hypersensitivity reaction to a previous dose of the vaccine or one of its components is a contraindication to the immunization of this vaccine. The local and systemic reactions of the type described in appendix D considered alone, do not represent significant hypersensitivity. Immunization is contraindicated in persons who develop reactions such as angioedema, generalized hives, or other manifestations of potentially life-threatening anaphylaxis. Persons manifesting these or similar reactions should not receive additional vaccine without prior consultation with an allergist or infectious disease specialist. Results of the consultation and any limitation on additional doses of the anthrax vaccine must be clearly documented in the individual medical record.

D-2. Warnings

a. Defer immunization for any person with an active infection with fever.

b. Immuno-suppressed individuals may not be adequately immunized. Individuals receiving a concurrent course of therapy that depresses the immune response, such as corticosteroids, may not be adequately immunized if the recommended dosage schedule is followed. For personnel with temporarily suppressed immune systems (due to therapy), immunization should be delayed during treatment.

c. Soldiers with HIV infection are not deployable and therefore are not likely to require anthrax immunization. There are no data on the safety or effectiveness of anthrax vaccine in HIV-infected individuals. Although the vaccine is likely to pose no risk to HIV-infected persons, the adequacy of the immune response to the vaccine in these persons is unknown. If clearly needed, anthrax vaccine should be administered to individuals with HIV infection. For example, a non-vaccinated individual with HIV infection who is exposed to anthrax spores should be immunized as part of post-exposure treatment.

D-3. Precautions

a. General. Routine immunization precautions against allergic and anaphylactic reaction should be followed IAW AR 40-562.

b. Pregnancy.

(1) Defer routine anthrax immunization during pregnancy. Although the risks associated with immunization during pregnancy are largely theoretical, prudence dictates that routine anthrax immunization be deferred during pregnancy. Pregnancy testing is not routinely indicated before administration of anthrax vaccine to women of childbearing age. IAW AR 40-562, para 11.1, each woman should be questioned before each injection as to whether she is or may be pregnant. If she states that she is pregnant or suspects that she might be, or is not sure, defer the immunization and refer her for evaluation of possible pregnancy. The series may by initiated or continued when the woman is no longer pregnant.

(2) Immunization during pregnancy. Like all other vaccines used in adults in the United States, anthrax vaccine is assigned by the FDA to Pregnancy Category C and may be given during pregnancy if clearly needed. Animal reproduction studies have not been conducted. It is not known if Anthrax Vaccine Adsorbed can cause fetal harm if administered to a pregnant woman or if it can affect reproduction capacity. Any episodes of immunization with anthrax vaccine during pregnancy must be documented in the woman's medical record. The woman should be counseled that although there is no data on anthrax vaccine during pregnancy,

inactivated viral and bacterial vaccines like Anthrax Vaccine Adsorbed are thought to pose very little risk to the woman or the fetus.

(3) Breast feeding (lactation). In accordance with ACIP guidelines for inactivated vaccines, there is no reason to interrupt breast feeding for immunization of a lactating mother with anthrax vaccine.

(4) Carcinogenesis, mutagenesis, impairment of fertility. To date, scientific studies have not been performed to determine whether Anthrax Vaccine Adsorbed has carcinogenic or mutagenic effects or any effect on fertility. There is no scientific evidence to suggest that anthrax vaccine, or any other inactivated vaccine should have such an effect. As with other inactivated vaccines, there is no medical reason to delay pregnancy following administration of anthrax vaccine.

c. Pediatric use/use in the elderly. Anthrax Vaccine Adsorbed is not approved for pediatric use (i.e., persons 17 years or younger) or older than 65 years of age. This vaccine should be administered only to healthy adults.

d. Blood donations. Immunization with Anthrax Vaccine Adsorbed does not affect blood donor status.

Appendix E
Adverse Reactions to Anthrax Vaccine

E-1. Local reactions

a. Mild local reactions occur in approximately 30% of recipients and consist of a small ring of erythema, 1 to 2 centimeters (cm) in diameter, plus slight local tenderness. This reaction usually occurs within 24 hours and begins to subside by 48 hours. Occasionally, the erythema increases to 3 to 5cm in diameter. Local reactions tend to increase in severity by the 5th injection and then may decrease in severity with subsequent doses.

b. Moderate local reactions which occur in 4% of recipients of a second injection are defined by an inflammatory reaction greater than 5cm in diameter which may itch. Subcutaneous nodules may occur at the injection site and persist for several weeks in some persons. A moderate local reaction can occur if the vaccine is given to anyone with a past history of anthrax infection.

c. More severe local reactions are less frequent and consist of extensive swelling of the forearm in addition to the local inflammatory reaction.

d. All local reactions described for this vaccine to date have been reversible.

E-2. Systemic reactions

Systemic reactions which occur in fewer than 0.2% of recipients have been characterized by tiredness and malaise. Chills and fever have been reported in only a few cases.

E-3. Supporting data

Clinical trials conducted by the Centers for Disease Control and Prevention (Department of Health and Human Services) involving approximately 16,500 doses of Anthrax Vaccine Adsorbed, indicated that the vaccine is safe. Despite an early study reporting reactions for 34% of recipients during the initial series, more recent studies report reactions in 3 to 14% of immunizations administered from several different lots of the vaccine and across several different years. Reports for booster doses were similar with reaction rates of 3 to 23% of booster doses administered.

a. Most reactions reported were local and mild in nature (i.e., erythema, edema, or induration which is measurable but 30 millimeters (mm) or less in any one diameter).

b. Severe local reactions (any reaction measuring more than 12cm in any one diameter or any reaction accompanied by marked limitation of motion of the arm or marked axillary tenderness) were reported for 1% or less of the doses given in any study during the 5-year period. Across all study periods, a total of only four systemic reactions were reported — two with chills and fever, one with fever, and one recipient reported feeling ill with general body aches for 24 hours. No chronic or permanent sequelae were reported for either the local reactions or the few systemic reactions encountered.

c. Clinical classification and management of adverse reactions should be done in accordance with the following outline:

(1) Severe – Automatic stop of further anthrax immunization

- Toxic Epidermal Necrolysis

- Erythema Multiforme (Minor and Major) – includes Stevens-Johnson Syndrome
- Neurologic Impairment (Guillain-Barre-Landry, etc.)

Recommendation – No further attempt to administer Anthrax Vaccine. No attempt to desensitize. Patient to be given permanent waiver.

(2) Moderate – Requires referral (starting with a telephonic communication) to an Allergist-Immunologist

- Systemic allergic reactions – generalized hives, angioedema, anaphylaxis
- Severe large local reactions – defined as >12 cm local inflammatory reaction

Recommendation – Telephonic communication with an Allergist – Immunologist must be made and disposition will be determined by the Allergist-Immunologist. Some patients will require referral to the allergist, others can be managed telephonically.

(3) Mild – Can be treated locally by an MTF provider

- Various size subcutaneous nodules
- Mild or moderate local reactions (<12 cm in size)
- Systemic "flu like symptoms" – fever, chills, myalgias, arthralgias, fatigue, etc.

Recommendation – Does not require consultation with an allergist-immunologist. Patients should be managed in a standard manner using the following guidelines:

- Subcutaneous nodules and mild/moderate local reactions
  - The patient can be treated acutely with a high-potency topical corticosteroid (clobetasol 0.05% cream preferred) and a non-steroidal anti-inflammatory drug such as ibuprofen 800mg PO TID for 24 – 48.
  - Prior to the next anthrax immunization, the soldier should be instructed to place the high-potency topical corticosteroid (clobetasol 0.05% cream preferred) on the arm where the next anthrax dose is to be given 24 hours before the injection and the morning of the injection. This strategy has been shown to be effective in preventing local reactions but not interfering with the systemic protective immune response to the vaccine.
  - Systemic corticosteroids **SHOULD NOT** be used for prophylaxis.
- Systemic flu-like symptoms (fever, chills, myalgias, malaise, etc.)
  - The patient can be acutely treated with acetaminophen 650mg – 1000mg by mouth every 4 to 6 hours as needed until symptoms resolve.
  - Prior to the next anthrax immunization, the patient should take acetaminophen 650 – 1000mg by mouth at least 1 hour prior to receiving the immunization. This strategy is effective in preventing mild systemic flu-like symptoms from vaccines without interfering with the systemic protective immune response to the vaccine. The acetaminophen can be continued every 4 to 6 hours as needed after the anthrax vaccination if breakthrough symptoms occur.

d. For referral purposes, allergist-immunologists are available within the NARMC at the following MTFs:

- Dewitt Army Community Hospital, Fort Belvoir, MAJ Ron DeGuzman, PH: 703-805-0188/0024
- Ireland Army Community Hospital, Fort Knox, LTC John Walker, PH: 502-624-9149/9160/9195
- Walter Reed Army Medical Center, Washington, DC (5 staff available), PH: 202-782-6849/6850
- Womack Army Medical Center, Ft. Bragg, MAJ Steve Pence, PH: 910-432-0767

Glossary

Section I
Abbreviations

AMEDD
U.S. Army Medical Department

AMSA
Army Medical Surveillance Activity

AVIP
Anthrax Vaccine Immunization Program

CHCS
Composite Health Care System

DA
Department of the Army

DCCS
Deputy Commander for Clinical Services

DEERS
Defense Enrollment Eligibility Reporting System

DoD
Department of Defense
HCT
health communication team

HHS
Health and Human Services

IAW
in accordance with

IMD
Information Management Division

KACC
Kimbrough Ambulatory Care Center

LOG
Logistics Division

MEDCOM
U.S. Army Medical Command

MEDDAC
U.S. Army Medical Department Activity, Fort George G. Meade

MEDPROS
Medical Protection System

MEDPROSCCT
MEDPROS configuration control team

MOPP
mission-oriented protection posture

MPD
Military Personnel Division

MTF
medical treatment facility

NARMC
North Atlantic Regional Medical Command

NCOIC
noncommissioned officer in charge

OMR
outpatient medical record

OSD
Operations & Staff Development Division
PHS
Public Health Service

PM
Preventive Medicine Service

PROFIS
Professional Filler System

RC
Reserve Component

USAHC
U.S. Army health clinic

USAMMA
U.S. Army Medical Materiel Agency

VAERS
Vaccine Adverse Event Reporting System

VAERS-1
VAERS report

WRAMC
Walter Reed Army Medical Center

Section II
Terms

Reserve Component
Within this regulation, the term "Reserve Component" includes the U.S. Army Reserve and National Guard, the U.S. Air Force Reserve and National Guard, the U.S. Navy Reserve and National Guard, and the U.S. Marine Corps Reserve and National Guard.